VOL 17 | ISSUE 1

Breast Cancer® UPDATE

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

Joyce O'Shaughnessy, MD

Erica L Mayer, MD, MPH

EDITOR

Neil Love, MD

Breast Cancer® UPDATE

Contact Information	Neil Love, MD Research To Practice One Biscayne Tower 2 South Biscayne Boulevard, Suite 3600 Miami, FL 33131 Fax: (305) 377-9998 Email: DrNeilLove@ResearchToPractice.com
For CME/CNE Information	Email: CE@ResearchToPractice.com

OVERVIEW OF ACTIVITY

Breast cancer (BC) continues to be one of the most rapidly evolving fields in medical oncology. Results from numerous ongoing trials lead to the continual emergence of new therapeutic agents, treatment strategies and diagnostic and prognostic tools. In order to offer optimal patient care, including the option of clinical trial participation, the practicing cancer clinician must be well informed of these advances. Featuring information on the latest research developments along with expert perspectives, this CME activity is designed to assist medical oncologists, hematologist-oncologists and hematology-oncology fellows with the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and emerging targeted treatments.
- Consider published data to guide the use of biomarkers and genomic assays to assess risk and individualize therapy for patients with hormone receptor-positive BC in the neoadjuvant, adjuvant and extended-adjuvant settings.
- Develop an evidence-based algorithm for the treatment of advanced, hormone receptor-positive, pre- and postmenopausal BC, including the use of endocrine, biologic and chemotherapeutic agents.
- Appreciate the recent FDA approvals of the PARP inhibitors olaparib and talazoparib for patients with HER2-negative metastatic BC and a germline BRCA mutation, and discern how these agents can be appropriately and safely integrated into routine clinical practice.
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials.

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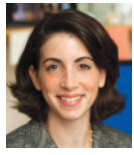
CME INFORMATION

FACULTY AFFILIATIONS

Joyce O'Shaughnessy, MD
Chair, Breast Cancer
Research Program
Baylor Charles A Sammons
Cancer Center
Celebrating Women Chair in
Breast Cancer Research
Texas Oncology
US Oncology
Dallas, Texas



Erica L Mayer, MD, MPH
Senior Physician
Susan F Smith Center for
Women's Cancers
Dana-Farber Cancer Institute
Assistant Professor in Medicine
Harvard Medical School
Boston, Massachusetts

EDITOR

Neil Love, MD
Research To Practice
Miami, Florida

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Interview with Joyce O'Shaughnessy, MD

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Track 2	Potential synergy of neratinib with endocrine therapy or capecitabine for ER-positive, HER2-positive mBC
Track 3	**Case:** A 56-year-old woman with heavily pretreated HER2-positive mBC develops thrombocytopenia after experiencing a complete response to T-DM1
Track 4	Exceptional clinical responses to HER2-targeted therapies
Track 5	Ongoing investigation of the biologic mechanisms underlying exceptional responses to HER2-targeted therapy
Track 6	**Case:** A 38-year-old woman with metastatic triple-negative BC (mTNBC) and a PI3KCA mutation achieves an excellent clinical response to irinotecan/carboplatin/cetuximab on a clinical trial
Track 7	Therapeutic approach for patients with ER-positive, HER2-positive mBC
Track 8	Duration of therapy for patients with ER-positive, HER2-positive mBC
Track 9	Use of CDK4/6 inhibitors for patients with ER-positive, HER2-positive BC
Track 10	Activity and side-effect profile of the highly selective tyrosine kinase inhibitor tucatinib in HER2-positive advanced BC
Track 11	**Case:** A 65-year-old woman with ER/PR-positive, HER2-negative BC receives a 21-gene assay Recurrence Score® (RS) of 24
Track 12	Selection of adjuvant endocrine therapy for premenopausal patients with ER-positive BC
Track 13	Incorporating TAILORx trial results in therapeutic decision-making with the 21-gene RS assay in ER-positive, HER2-negative, node-negative BC
Track 14	**Case:** A 45-year-old woman with ER-positive, HER2-negative BC and metastases to the liver and bones receives abemaciclib and fulvestrant
Track 15	Efficacy and tolerability of abemaciclib for ER-positive mBC
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Track 17	Choice of endocrine therapy to partner with a CDK4/6 inhibitor for ER-positive mBC
Track 18	Promising antibody-drug conjugates under investigation for BC
Track 19	Role of checkpoint inhibitors for patients with mTNBC
Track 20	Indications for BRCA mutation testing in patients with BC
Track 21	Side effects associated with PARP inhibitors
Track 22	**Case:** A 30-year-old woman with TNBC and a solitary metastasis to the liver receives eribulin and capecitabine
Track 23	Efficacy of eribulin for patients with TNBC
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Interview with Erica L Mayer, MD, MPH

Tracks 1-22

Track 1	Preliminary results from the Phase III KATHERINE study evaluating T-DM1 versus trastuzumab as adjuvant therapy for patients with HER2-positive early BC and residual disease after preoperative therapy
Track 2	Side effects and quality of life associated with T-DM1 treatment
Track 3	**Case:** A 57-year-old postmenopausal woman with an ER/PR-positive, HER2-positive infiltrating ductal carcinoma (IDC) and positive axillary lymph nodes achieves a clinical response to neoadjuvant paclitaxel/trastuzumab/pertuzumab (THP)
Track 4	Therapeutic options for patients with ER-positive, HER2-positive BC in the (neo)adjuvant setting
Track 5	Efficacy of CDK4/6 inhibitors for patients with ER-positive, HER2-negative mBC

Interview with Dr Mayer (continued)

Track 6 Benefits and risks with the addition of CDK4/6 inhibitors to hormone therapy

Track 7 Perspective on the use of CDK4/6 inhibitors for elderly patients

Track 8 Activity and tolerability of palbociclib, abemaciclib and ribociclib

Track 9 Dosing considerations and adherence to treatment with CDK4/6 inhibitors

Track 10 Activity of CDK4/6 inhibitors in patients with brain metastases

Track 11 Ongoing Phase II PACE study evaluating the addition of palbociclib with or without avelumab to fulvestrant for patients who experience disease progression on a CDK4/6 inhibitor and endocrine therapy

Track 12 Selection and sequencing of CDK4/6 inhibitors for patients with ER-positive, HER2-negative mBC

Track 13 **Case:** A 58-year-old postmenopausal woman with a Grade III, ER/PR-positive, HER2-negative IDC and a RS of 12

Track 14 Use of the 21-gene RS assay for patients with node-positive BC

Track 15 Choice of endocrine therapy for premenopausal women with node-positive BC

Track 16 Role of chemotherapy for patients with ER-positive, node-positive BC and an intermediate RS

Track 17 Perspective on using genomic assays for ER-positive, HER2-negative, node-negative BC in the neoadjuvant setting

Track 18 IMpassion130: A Phase III trial of atezolizumab with *nab* paclitaxel as first-line treatment for advanced TNBC

Track 19 **Case:** A 55-year-old woman with ER/PR-positive, HER2-negative mBC and a germline BRCA2 mutation receives olaparib after disease progression on several lines of therapy

Track 20 Efficacy of the PARP inhibitors talazoparib and olaparib in patients with BC and a germline BRCA mutation

Track 21 Prognosis and outcomes for patients with pregnancy-associated BC

Track 22 **Case:** A 32-year-old woman who is 12 weeks pregnant presents with a palpable breast mass and is diagnosed with ER-positive, HER2-positive BC

Video Program

View the corresponding video interviews with (from left) Drs O'Shaughnessy and Mayer by Dr Love at www.ResearchToPractice.com/BCU318/Video

SELECT PUBLICATIONS

A phase III, multicenter, randomized, open-label study comparing atezolizumab (anti PD-L1 antibody) in combination with adjuvant anthracycline/taxane-based chemotherapy versus chemotherapy alone in patients with operable triple negative breast cancer. NCT03498716

A phase III, multicenter, randomized, placebo-controlled study of atezolizumab (anti-PD-L1 antibody) in combination with *nab*-paclitaxel compared with placebo with *nab*-paclitaxel for patients with previously untreated metastatic triple-negative breast cancer. NCT02425891

A phase III, randomized clinical trial of standard adjuvant endocrine therapy +/- chemotherapy in patients with 1-3 positive nodes, hormone receptor-positive and HER2-negative breast cancer with Recurrence Score (RS) of 25 or less. RxPONDER: A clinical trial Rx for positive node, endocrine responsive breast cancer. NCT01272037

A phase III, randomized, double-blind study to evaluate pembrolizumab plus chemotherapy vs placebo plus chemotherapy as neoadjuvant therapy and pembrolizumab vs placebo as adjuvant therapy for triple negative breast cancer (TNBC). NCT03036488

Albain KS et al. **Prognostic and predictive value of the 21-gene Recurrence Score assay in postmenopausal women with node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: A retrospective analysis of a randomised trial**. *Lancet Oncol* 2010;11(1):55-65.

Bardia A et al. **A phase III, randomized trial of sacituzumab govitecan (IMMU-132) vs treatment of physician choice (TPC) for metastatic triple-negative breast cancer (mTNBC).** San Antonio Breast Cancer Symposium 2017;**Abstract OT2-07-05**.

Bardia A et al. **Efficacy and safety of anti-trop-2 antibody drug conjugate sacituzumab govitecan (IMMU-132) in heavily pretreated patients with metastatic triple-negative breast cancer.** *J Clin Oncol* 2017;35(19):2141-8.

Ejlertsen B et al. **Timing of initiation of neratinib after completion of trastuzumab-based adjuvant therapy in early-stage HER2+ breast cancer: Exploratory analyses from the phase III ExteNET trial.** San Antonio Breast Cancer Symposium 2017;**Abstract P1-13-05**.

Freedman RA et al. **TBCRC 022: Phase II trial of neratinib + capecitabine for patients (Pts) with human epidermal growth factor receptor 2 (HER2+) breast cancer brain metastases (BCBM).** *Proc ASCO* 2017;**Abstract 1005**.

Litton JK et al. **Talazoparib in patients with advanced breast cancer and a germline BRCA mutation.** *N Engl J Med* 2018;379(8):753-63.

Murthy R et al. **Tucatinib with capecitabine and trastuzumab in advanced HER2-positive metastatic breast cancer with and without brain metastases: A non-randomised, open-label, phase 1b study.** *Lancet Oncol* 2018;19(7):880-8.

Neven P et al. **Abemaciclib for pre/perimenopausal women with HR+, HER2- advanced breast cancer.** *Proc ASCO* 2018;**Abstract 1002**.

Regan MM et al. **Absolute improvements in freedom from distant recurrence with adjuvant endocrine therapies for premenopausal women with hormone receptor-positive (HR+) HER2-negative breast cancer (BC): Results from TEXT and SOFT.** *Proc ASCO* 2018;**Abstract 503**.

Rimawi M et al. **First-line trastuzumab plus an aromatase inhibitor, with or without pertuzumab, in human epidermal growth factor receptor 2-positive and hormone receptor-positive metastatic or locally advanced breast cancer (PERTAIN): A randomized, open-label phase II trial.** *J Clin Oncol* 2018;36(28):2826-35.

Robson M et al. **Olaparib for metastatic breast cancer in patients with a germline BRCA mutation.** *N Engl J Med* 2017;377(6):523-33.

Slamon DJ et al. **Ribociclib (RIB) + fulvestrant (FUL) in postmenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2–) advanced breast cancer (ABC): Results from MONALEESA-3.** *Proc ASCO* 2018;**Abstract 1000**.

Smith J II et al. **Phase 2 study evaluating the efficacy and safety of eribulin mesylate administered biweekly for patients with human epidermal growth factor receptor 2-negative metastatic breast cancer.** San Antonio Breast Cancer Symposium 2017;**Abstract P6-14-05**.

Sparano JA et al. **Adjuvant chemotherapy guided by a 21-gene expression assay in breast cancer.** *N Engl J Med* 2018;379(2):111-21.

Stearns V. **TAILORing adjuvant systemic therapy for breast cancer.** *N Engl J Med* 2018;379(2):191-2.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Results of the Phase III IMpassion 130 trial, which were presented at ESMO 2018 and published in *The New England Journal of Medicine*, demonstrated a statistically significant improvement in _____ with the addition of atezolizumab to *nab* paclitaxel as first-line treatment for advanced TNBC.**
   a. Overall survival
   b. Progression-free survival
   c. Both a and b
   d. Neither a nor b

2. **The TEXT and SOFT trials reported a statistically significant improvement in freedom from distant recurrence among premenopausal women with ER-positive BC who received exemestane and ovarian function suppression compared to tamoxifen alone.**
   a. True
   b. False

3. **Results from the Phase II PERTAIN study for ER-positive, HER2-positive locally advanced or metastatic BC demonstrated a statistically significant improvement in progression-free survival with the addition of _____ to first-line trastuzumab and an aromatase inhibitor.**
   a. Neratinib
   b. Pertuzumab
   c. Pembrolizumab

4. **The APHINITY trial investigating the addition of pertuzumab to adjuvant trastuzumab and chemotherapy for HER2-positive early BC demonstrated better outcomes for patients with node-negative BC than for those with node-positive BC.**
   a. True
   b. False

5. **The ongoing Phase II HER2CLIMB study is evaluating the addition of tucatinib to _____ for advanced HER2-positive BC.**
   a. Capecitabine
   b. Trastuzumab
   c. Both a and b

6. **In the Phase III TAILORx study for patients with node-negative, hormone receptor-positive, HER2-negative BC and an intermediate RS of 11 to 25, adjuvant endocrine therapy alone was _____ to endocrine therapy with chemotherapy in terms of invasive disease-free survival in the postmenopausal population.**
   a. Inferior
   b. Noninferior

7. **Patients who are pregnant and have been diagnosed with HER2-positive BC _____.**
   a. Can receive trastuzumab/pertuzumab with chemotherapy during pregnancy
   b. Can receive chemotherapy during the second and third trimesters followed by trastuzumab/pertuzumab after delivery

8. **Which Phase III trial is evaluating T-DM1 versus trastuzumab as adjuvant therapy for patients with HER2-positive early BC and residual disease after preoperative therapy?**
   a. APHINITY
   b. HER2CLIMB
   c. KATHERINE

9. **Which of the following categories reflects the mechanism of action of tucatinib?**
   a. Antibody-drug conjugate
   b. Anti-PD-1/PD-L1 antibody
   c. CDK4/6 inhibitor
   d. Tyrosine kinase inhibitor

10. **Results from the Phase III PALOMA-3 study, which were presented at ESMO 2018 and published in *The New England Journal of Medicine*, included a statistically significant improvement in overall survival with the addition of palbociclib to fulvestrant for patients with hormone receptor-positive, HER2-negative advanced BC who were sensitive to previous endocrine therapy.**
    a. True
    b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update — Volume 17, Issue 1

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PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
TAILORx: Results of a Phase III study of chemoendocrine therapy versus endocrine therapy alone for patients with node-negative, hormone receptor-positive, HER2-negative BC and an intermediate 21-gene assay RS	4 3 2 1	4 3 2 1
Available data with and choice among the FDA-approved CDK4/6 inhibitors abemaciclib, palbociclib and ribociclib for ER-positive mBC	4 3 2 1	4 3 2 1
Activity and side-effect profile of the HER2-selective tyrosine kinase inhibitor tucatinib for HER2-positive advanced BC	4 3 2 1	4 3 2 1
IMpassion130: An ongoing Phase III study of atezolizumab and *nab* paclitaxel as first-line therapy for advanced TNBC	4 3 2 1	4 3 2 1
Efficacy of talazoparib in patients with BC and a germline BRCA mutation	4 3 2 1	4 3 2 1

Practice Setting:

⬭ Academic center/medical school ⬭ Community cancer center/hospital ⬭ Group practice

⬭ Solo practice ⬭ Government (eg, VA) ⬭ Other (please specify).....

Approximately how many new patients with breast cancer do you see per year? ..... patients

Was the activity evidence based, fair, balanced and free from commercial bias?

⬭ Yes ⬭ No If no, please explain: .....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

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⬭ Create/revise protocols, policies and/or procedures

⬭ Change the management and/or treatment of my patients

⬭ Other (please explain): .....

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.....

.....

The content of this activity matched my current (or potential) scope of practice.

⬭ Yes ⬭ No If no, please explain: .....

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

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As a result of this activity, I will be able to:

- Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing, recently approved and emerging targeted treatments..... 4 3 2 1 N/M N/A
- Consider published data to guide the use of biomarkers and genomic assays to assess risk and individualize therapy for patients with hormone receptor-positive BC in the neoadjuvant, adjuvant and extended-adjuvant settings..... 4 3 2 1 N/M N/A
- Develop an evidence-based algorithm for the treatment of advanced, hormone receptor-positive, pre- and postmenopausal BC, including the use of endocrine, biologic and chemotherapeutic agents..... 4 3 2 1 N/M N/A

As a result of this activity, I will be able to:

- Appreciate the recent FDA approvals of the PARP inhibitors olaparib and talazoparib for patients with HER2-negative metastatic BC and a germline BRCA mutation, and discern how these agents can be appropriately and safely integrated into routine clinical practice. . . . . 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials. . . . . 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

. . . . . .

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☐ Yes ☐ No

If no, please explain: . . . . . .

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Joyce O'Shaughnessy, MD	4 3 2 1	4 3 2 1
Erica L Mayer, MD, MPH	4 3 2 1	4 3 2 1
Editor	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

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Neil Love, MD
Research To Practice
One Biscayne Tower
2 South Biscayne Boulevard, Suite 3600
Miami, FL 33131

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